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801
802 Lamivudine is manufactured under agreement from
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804 Basingstoke, UK
805

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811 **MEDICATION GUIDE**

812 **EPZICOM[®] (ep' zih com)**

813 (abacavir sulfate and lamivudine)

814 **Tablets**

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816 Read this Medication Guide before you start taking EPZICOM and each time you get
817 a refill. There may be new information. This information does not take the place of
818 talking to your healthcare provider about your medical condition or your treatment.
819 Be sure to carry your EPZICOM Warning Card with you at all times.

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821 **What is the most important information I should know about EPZICOM?**

822 **1. Serious allergic reaction (hypersensitivity reaction).** EPZICOM contains
823 abacavir (also contained in ZIAGEN[®] and TRIZIVIR[®]). Patients taking EPZICOM
824 may have a serious allergic reaction (hypersensitivity reaction) that can cause
825 death. Your risk of this allergic reaction is much higher if you have a gene
826 variation called HLA-B*5701. Your healthcare provider can determine with a
827 blood test if you have this gene variation.

828 **If you get a symptom from 2 or more of the following groups while**
829 **taking EPZICOM, call your healthcare provider right away to find out**
830 **if you should stop taking EPZICOM.**

	Symptom(s)
Group 1	Fever
Group 2	Rash
Group 3	Nausea, vomiting, diarrhea, abdominal (stomach area) pain
Group 4	Generally ill feeling, extreme tiredness, or achiness
Group 5	Shortness of breath, cough, sore throat

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A list of these symptoms is on the Warning Card your pharmacist gives you.
Carry this Warning Card with you at all times.

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If you stop EPZICOM because of an allergic reaction, never take EPZICOM (abacavir sulfate and lamivudine) or any other abacavir-containing medicine (ZIAGEN and TRIZIVIR) again. If you take EPZICOM or any other abacavir-containing medicine again after you have had an allergic reaction, **within hours** you may get **life-threatening symptoms** that may include **very low blood pressure** or **death**. If you stop EPZICOM for any other reason, even for a few days, and you are not allergic to EPZICOM, talk with your healthcare provider before taking it again. Taking EPZICOM again can cause a serious allergic or life-threatening reaction, even if you never had an allergic reaction to it before.

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If your healthcare provider tells you that you can take EPZICOM again, start taking it when you are around medical help or people who can call a healthcare provider if you need one.

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- 2. Lactic Acidosis (buildup of acid in the blood). Some human immunodeficiency virus (HIV) medicines, including EPZICOM, can cause a rare but serious condition called lactic acidosis. Lactic acidosis is a serious medical emergency that can cause death and must be treated in the hospital.**

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Call your healthcare provider right away if you get any of the following signs or symptoms of lactic acidosis:

- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you have stomach pain with nausea and vomiting

- 859 • you feel cold, especially in your arms and legs
- 860 • you feel dizzy or light-headed
- 861 • you have a fast or irregular heartbeat

862 **3. Serious liver problems. Some people who have taken medicines like**
863 **EPZICOM have developed serious liver problems called hepatotoxicity,**
864 **with liver enlargement (hepatomegaly) and fat in the liver (steatosis).**
865 **Hepatomegaly with steatosis is a serious medical emergency that can**
866 **cause death.**

867 **Call your healthcare provider right away if you get any of the**
868 **following signs or symptoms of liver problems:**

- 869 • your skin or the white part of your eyes turns yellow (jaundice)
- 870 • your urine turns dark
- 871 • your bowel movements (stools) turn light in color
- 872 • you don't feel like eating food for several days or longer
- 873 • you feel sick to your stomach (nausea)
- 874 • you have lower stomach area (abdominal) pain

875 **You may be more likely to get lactic acidosis or serious liver**
876 **problems if you are female, very overweight, or have been taking**
877 **nucleoside analogue medicines for a long time.**

878 **4. Use with interferon and ribavirin-based regimens.** Worsening of liver
879 disease (sometimes resulting in death) has occurred in patients infected with
880 both HIV and hepatitis C virus who are taking anti-HIV medicines and are also
881 being treated for hepatitis C with interferon with or without ribavirin. If you are
882 taking EPZICOM as well as interferon with or without ribavirin and you
883 experience side effects, be sure to tell your healthcare provider.

884 **5. If you have HIV and hepatitis B virus infection, your hepatitis B virus**
885 **infection may get worse if you stop taking EPZICOM.**

- 886 • Take EPZICOM exactly as prescribed.
- 887 • Do not run out of EPZICOM.
- 888 • Do not stop EPZICOM without talking to your healthcare provider.
- 889 • Your healthcare provider should monitor your health and do regular blood
890 tests to check your liver if you stop taking EPZICOM.

891 **What is EPZICOM?**

892 EPZICOM is a prescription medicine used to treat HIV infection. EPZICOM contains
893 2 medicines: abacavir (ZIAGEN) and lamivudine or 3TC (EPIVIR®). Both of these
894 medicines are called nucleoside analogue reverse transcriptase inhibitors (NRTIs).
895 When used together, they help lower the amount of HIV in your blood.

- 896 • **EPZICOM does not cure HIV infection or AIDS.**
- 897 • It is not known if EPZICOM will help you live longer or have fewer of the medical
- 898 problems that people get with HIV or AIDS.
- 899 • It is very important that you see your healthcare provider regularly while you
- 900 are taking EPZICOM.
- 901 • It is not known if EPZICOM is safe or effective in children under the age of 18.

902 **Who should not take EPZICOM?**

903 **Do not take EPZICOM if you:**

- 904 • **are allergic to abacavir or any of the ingredients in EPZICOM. See the**
- 905 **end of this Medication Guide for a complete list of ingredients in**
- 906 **EPZICOM.**
- 907 • **have certain liver problems**

908 **What should I tell my healthcare provider before taking EPZICOM?**

909 **Before you take EPZICOM tell your healthcare provider if you:**

- 910 • **have been tested and know whether or not you have a particular gene**
- 911 **variation called HLA-B*5701**
- 912 • **have hepatitis B virus infection or have other liver problems**
- 913 • **have kidney problems**
- 914 • **have heart problems, smoke, or have diseases that increase your risk of**
- 915 **heart disease such as high blood pressure, high cholesterol, or diabetes.**
- 916 • **are pregnant or plan to become pregnant.** It is not known if EPZICOM will
- 917 harm your unborn baby. Talk to your healthcare provider if you are pregnant or
- 918 plan to become pregnant.

919 **Pregnancy Registry.** If you take EPZICOM while you are pregnant, talk to your

920 healthcare provider about how you can take part in the Pregnancy Registry for

921 EPZICOM. The purpose of the pregnancy registry is to collect information about

922 the health of you and your baby.

- 923 • **are breastfeeding or plan to breastfeed.** EPZICOM can pass into your breast
- 924 milk. You should not breastfeed if you are taking EPZICOM. If you are a woman
- 925 who has or will have a baby while taking EPZICOM, talk to your healthcare
- 926 provider about the best way to feed your baby. The Center for Disease Control
- 927 and Prevention (CDC) recommend that HIV-infected mothers **not** breastfeed to
- 928 avoid the risk of passing HIV infection to your baby.

929 **Tell your healthcare provider about all the medicines you take,** including

930 prescription and nonprescription medicines, vitamins, and herbal supplements.

931 **Especially tell your healthcare provider if you take:**

- 932 • alcohol
- 933 • medicines used to treat hepatitis viruses such as interferon or ribavirin.
- 934 • methadone
- 935 • ATRIPLA[®] (efavirenz, emtricitabine, and tenofovir)
- 936 • COMBIVIR[®] (lamivudine and zidovudine)
- 937 • EMTRIVA[®] (emtricitabine)
- 938 • EPIVIR or EPIVIR-HBV[®] (lamivudine, 3TC)
- 939 • TRIZIVIR (abacavir sulfate, lamivudine, and zidovudine)
- 940 • TRUVADA[®] (emtricitabine and tenofovir)
- 941 • ZIAGEN (abacavir sulfate)

942 Ask your healthcare provider if you are not sure if you take one of the medicines
943 listed above.

944 EPZICOM may affect the way other medicines work, and other medicines may affect
945 how EPZICOM works.

946 Know the medicines you take. Keep a list of your medicines with you to show to
947 your healthcare provider and pharmacist when you get a new medicine.

948 **How should I take EPZICOM?**

- 949 • **Take EPZICOM exactly as your healthcare provider tells you to take it.**
- 950 • EPZICOM may be taken with or without food.
- 951 • Do not skip doses.
- 952 • **Do not let your EPZICOM run out.**

953 If you stop your anti-HIV drugs, even for a short time, the amount of virus in your
954 blood may increase and the virus may become harder to treat. If you take too
955 much EPZICOM, call your healthcare provider or poison control center or go to the
956 nearest hospital emergency room right away

957 **What are the possible side effects of EPZICOM?**

- 958 • **EPZICOM can cause serious side effects including allergic reactions,**
959 **lactic acidosis, and liver problems. See “What is the most important**
960 **information I should know about EPZICOM?”**
- 961 • **Changes in immune system (Immune Reconstitution Syndrome).** Your
962 immune system may get stronger and begin to fight infections that have been
963 hidden in your body for a long time. Tell your healthcare provider if you start
964 having new or worse symptoms of infection after you start taking EPZICOM.

965 • **Changes in body fat (fat redistribution).** Changes in body fat (lipoatrophy or
966 lipodystrophy) can happen in some people taking antiretroviral medicines
967 including EPZICOM.

968 These changes may include:

- 969 ○ more fat in or around your trunk, upper back and neck (buffalo hump),
970 breast, or chest
- 971 ○ loss of fat in your legs, arms, or face

972 • **Heart attack (myocardial infarction).** Some HIV medicines including
973 EPZICOM may increase your risk of heart attack.

974 **The most common side effects of EPZICOM include:**

- 975 • trouble sleeping
- 976 • depression
- 977 • headache
- 978 • tiredness
- 979 • dizziness
- 980 • nausea
- 981 • diarrhea
- 982 • rash
- 983 • fever

984 Tell your healthcare provider if you have any side effect that bothers you or that
985 does not go away.

986 These are not all the possible side effects of EPZICOM. For more information, ask
987 your healthcare provider or pharmacist.

988 Call your doctor for medical advice about side effects. You may report side effects
989 to FDA at 1-800-FDA-1088.

990 **How should I store EPZICOM?**

991 Store EPZICOM at 59°F to 86°F (15°C to 30°C).

992 **Keep EPZICOM and all medicines out of the reach of children.**

993 **General information for safe and effective use of EPZICOM.**

994 **EPZICOM does not stop you from spreading HIV to other people by sex,**
995 **sharing needles, or being exposed to your blood.** Talk with your healthcare
996 provider about safe sexual practices that protect your partner. Never share needles.

997 Do not share personal items that can have blood or body fluids on them, like
998 toothbrushes or razor blades.

999 Medicines are sometimes prescribed for purposes other than those listed in a
1000 Medication Guide. Do not use EPZICOM for a condition for which it was not
1001 prescribed. Do not give EPZICOM to other people, even if they have the same
1002 symptoms that you have. It may harm them.

1003 This Medication Guide summarizes the most important information about EPZICOM.
1004 If you would like more information, talk with your healthcare provider. You can ask
1005 your healthcare provider or pharmacist for the information about EPZICOM that is
1006 written for healthcare professionals.

1007 For more information go to www.EPZICOM.com or call 1-877-844-8872.

1008 **What are the ingredients in EPZICOM?**

1009 Active ingredients: abacavir sulfate and lamivudine

1010 Inactive ingredients: magnesium stearate, microcrystalline cellulose, sodium starch
1011 glycolate, and OPADRY® orange YS-1-13065-A, a film coating made of FD&C Yellow
1012 No. 6, hypromellose, polyethylene glycol 400, polysorbate 80, and titanium dioxide.

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1017 endorse ViiV Healthcare or its products.

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1020 Manufactured for:



1021

1022 ViiV Healthcare

1023 Research Triangle Park, NC 27709

1024 by:



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1031 This Medication Guide has been approved by the US Food and Drug Administration.

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